At the outset, applicants appreciate the Examiner's statement that the previous rejections of record have all been withdrawn.

The Examiner has objected to the specification since there appears to be an informality on page 16 with respect to example 8 of table 1 in terms of the R_3 group. Accordingly, applicants have amended the chemical formula on page 16 to indicate the final hydrogen atom.

There is one outstanding rejection of record. Claims 29-32 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 5-7 of U.S. Patent No. 4,963,590. This rejection is respectfully traversed.

Applicants would like to provide a brief history of the prosecution of the application which issued as U.S. Patent No. 4,963,590. It is readily apparent when reviewing the prosecution of that application that the compound claims and the composition claims were considered patentably distinct consistently throughout the prosecution of the application.

U.S. Serial No. 126,911, which finally issued as U.S. Patent No. 4,963,590, was filed in the U.S. Patent and Trademark Office on November 27, 1987. Original claims 1-21 were compound claims. Original claims 22-24 were method or process claims for the preparation of a compound. Claims 25-28 were pharmaceutical composition of matter claims.

A preliminary amendment was filed amending claim 1 to convert it from a compound to a pharmaceutical composition of matter claim. Claims 2-21 which depended

on claim 1 were retained as compound claims by applicants' previous attorneys. New pharmaceutical composition of matter claims 28 and 29 were also introduced. In addition, new claim 30 which is a method of use claim was added and new compound claim 31 was added to the application.

Next a Requirement for Restriction in an Official Action mailed January 11, 1989 by Examiner Richter restricted the application to the following:

Group I - compositions and method of use according to claims 1-20 and 24-31.

Group II - the process according to claims 21-23.

Applicants responded to the Requirement for Restriction by electing Group I. In addition, new compound claim 32 was introduced in the application. (Applicants note that new compound claim 32 appears to suggest that claim 1 is also a compound claim, however, claim 1 was actually amended as a pharmaceutical composition of matter in the previous response. This inconsistency was addressed in later prosecution.)

The application was transferred to Examiner Friedman and Examiner Friedman mailed an Official Action on August 28, 1989. In that Official Action, Examiner Friedman acknowledged applicants' election of Group I and stated that claims 21-23 and 31-32 were withdrawn under 37 C.F.R. § 1.142. Therefore, those claims were withdrawn because they were directed to patentably distinct subject matter. Examiner Friedman acknowledged that claim 1 was amended to recite a pharmaceutical composition of matter. Examiner Friedman recited in the middle of page 2 of his Official Action that claims 2-20 should also state a pharmaceutical composition of matter. This is consistent with Examiner Friedman's interpretation of the Requirement for Restriction since

compounds claims 31 and 32 were withdrawn from consideration since they were compound claims and they were considered to be patentably distinct.

Applicants' representative then conducted a personal interview with Examiner Friedman on November 15, 1989. The Examiner Interview Summary Record indicates that Examiner Friedman agreed that the pharmaceutical compositions of the matter claims would be allowable.

Applicants then filed an amendment cancelling claim 1 and replacing pharmaceutical composition of matter claim 1 with pharmaceutical composition of matter claim 33. For an unknown reason, applicants' representative amended compound claims 31 and 32, however, claims 31 and 32 were still compound claims. Kindly note that these two claims were indicated as being withdrawn from consideration by Examiner Friedman since they were considered to be directed to patentably distinct subject matter.

Examiner Friedman then issued an Official Action on January 11, 1990 and at the top of page 2 of the Official Action repeated, "Claims 21-23 and 31-32 remain withdrawn under 37 C.F.R. 1.142(b)." Thus, Examiner Friedman is maintaining his position that the compound claims are patentably distinct. Examiner Friedman also retained his rejection of claims 2-20 under 35 U.S.C. § 112, second paragraph, since applicants did not amend claims 2-20 in their previous response to recite a pharmaceutical composition of matter.

Applicants' undersigned representative then assumed responsibility for the subject application and an interview was conducted with Examiners Friedman and Shen on March 16, 1990. During that interview, Examiner Friedman indicated that he was willing to

examine and allow claims directed to pharmaceutical compositions of matter and methods of use. Examiner Friedman further explained that Examiner Shen was present at the interview since she would later examine the divisional application directed to the compound claims. Applicants' undersigned representative made a notation to this effect on the top of her copy of the Examiner Interview Summary Record. That Examiner Interview Summary Record as completed by Examiner Friedman confirms that applicants' undersigned representative agreed to submit claims which were directed to compositions and method of use.

Applicants' undersigned representative then filed an amendment in the U.S. Patent and Trademark Office on March 30, 1990 wherein an entirely new set of claims were presented for consideration by Examiner Friedman. New independent pharmaceutical composition of matter claims 34, 35 and 41 were added. In addition, dependent pharmaceutical composition of matter claims 36-40 were introduced in the application. Further, as discussed during the interview, pharmaceutical method of use claims 42-49 were added to the application. In applicants' remarks at the bottom of page 5, applicant stated the following:

> During the interview, Examiner Friedman agreed to allow composition and method claims directed to two single species of compounds.

Thus, Examiner Friedman emphasized that the subject application could only be directed to composition of matter and method claims. Further, as stated in the second full paragraph from the bottom on page 7 of applicants' response, the undersigned stated:

> Applicants reserve the right to file divisional applications directed to the compound claims as well as composition and method claims which do not fall within the scope of the newly presented claims.

Thus, the entire theme of the prosecution of the application which eventually led to the issuance of U.S. Patent No. 4,963,590 was consistent in maintaining the pharmaceutical composition of matter claims distinct from the compound claims. In view of the Requirement for Restriction and how it was interpreted by the Examiner and applicants, a Terminal Disclaimer is not necessary.

In view of the foregoing, applicants maintain that the double patenting rejection should be withdrawn and there is no need for applicants to file a terminal disclaimer in the subject application.

From the foregoing, further and favorable action in the form of a notice of allowance directed to claims 29-32 is believed to be next in order, and such action is earnestly solicited.

If the Examiner has any questions concerning the subject application, she is respectfully requested to telephone the undersigned attorney at the below listed number.

Respectfully submitted,

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